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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/647,243 | 08/26/2003 | Jean-Christophe Leroux | 017753-165 | 1768 |

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| EXAMINER | |
|---|---|
| TSAY, MARSHA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/647,243 | LEROUX ET AL. | |
| | Examiner | Art Unit | |
| | Marsha M. Tsay | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,14-18 and 22-28* is/are rejected.

7)☒ Claim(s) *2,9,13 and 19-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-28 are pending and under examination.

Priority: The instant application was filed August 26, 2003. This application claims priority to provisional application 60/405,720, filed August 26, 2002, and foreign priority to PCT/FR03/00797, filed March 12, 2003. The foreign application has been submitted. The priority date is August 26, 2002.

### *Specification*

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/405,720, filed August 26, 2002, and Foreign Application PCT/FR03/00797, filed March 12, 2003. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the

prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 27 is drawn to a process for preparing an organogel composition. It is unclear whether the process is “comprising the steps of” or is “consisting of” the steps as disclosed in the claim.

Claim 28 is objected to because it is unclear whether the “said substance” is referring to the organogelling substance or the bioactive substance. In addition, the term “sparingly” soluble renders the claim indefinite because there is no explicit definition of “sparingly” and it is uncertain to what extent and the difference in degree, if any, between a substance that is soluble as opposed to one that is “sparingly” soluble.

## *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10-12, 14-18, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarantino (WO 9408623). Tarantino teaches injectable compositions for the sustained release of biologically active proteins and polypeptides. The lecithin gel can be formed in vivo by the intramuscular or subcutaneous injection of a solution of

lecithin in an organic solvent (p. 1, lines 30-32). Tarantino teach the lecithin gels are formed in vivo by absorption of water from the aqueous interstitial fluid at the injection site (p. 2, lines 1-3). Tarantino teach the injectable pharmaceutical composition which forms a lecithin gel in vivo for the sustained release of a biologically active compound to comprise of: 1) a pharmaceutically acceptable organic solvent which is not substantially soluble in water and which is capable of dispersing a lecithin and forming a lecithin gel upon the absorption of body fluids; 2) a biologically active compound; and 3) a lecithin dispersed in the organic solvent in an amount sufficient to cause gelation upon the absorption of body fluids (p. 3, lines 1-13; claims 1, 3). Tarantino teaches the term "lecithin" to encompass a complex mixture of acetone-insoluble phosphatides which consists chiefly of phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine, etc., combined with various substances such as triglycerides, fatty acids, and carbohydrates (p. 3, lines 25-30). Tarantino also teaches that the composition can contain additional substances that further stabilize the active ingredient (p. 5, lines 21-28) or comprise excipients which act to modify the properties of the lecithin gel (p. 6). Tarantino teaches an injectable composition (example 1a) containing 0.148 mL Interferon $\alpha$-2a; 0.052 mL ammonium acetate pH 5.0; 6.0 g lecithin; and 14.8 g medium chain triglycerides (MCT) (p. 10, example 1; claims 1, 3, 6-8, 14-18). Tarantino teaches the MCT to comprise of fractionated coconut oil fatty acids $C_8$-$C_{10}$ which contains 50-65% caprylic acid and 30-45% capric acid, etc. (p. 5, lines 7-10; claims 10-12).

Tarantino teaches the subcutaneous administration of the composition from example 1a, containing IFN-$\alpha$, to rats (p. 14, lines 5-7; claims 23-25). In Figure 1,

Tarantino demonstrates that the sustained release composition of example 1a provided detectable serum levels for at least 96 hours (p. 14, lines 24-26), indicating the the organogel is in a stable gel form (claim 22).

Tarantino teaches a process for preparing an injectable composition that can form a gel in vivo by intramuscular or subcutaneous injection into an animal body. Tarantino teaches that if the active ingredient is not readily dispersible in the lecithin/solvent mixture, the active ingredient may first be dissolved in a small amount of water or in a buffer solution (p. 7, lines 10-14; claim 26).

Although Tarantino does not teach the transition temperature of the organogel from the liquid state to the gel state, this property is inherent to the lecithin gels and meets the limitations of claims 4-5 because the lecithin organogel that Tarantino teaches, meets the limitations of claim 1, and changes from the liquid to the gel state upon injection into an animal body (p. 14, example 2).

## ***Claim Objections***

Claims 2, 9, 13, 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 30, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER